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A potential solution for detecting missed breast cancer

PRINCIPAL INVESTIGATOR: Matthew T. Freedman, M.D.

CONTRACTING ORGANIZATION: Georgetown University Medical Center
                            Washington, DC   20057

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Matthew T. Freedman, M.D.

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Georgetown University Medical Center
Washington, DC 20057
email Freedmmt@georgetown.edu

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The Imperium Inc transmission ultrasound system is a highly promising novel method for imaging the breast. In this pilot project, we are to work with Imperium to advise and help them modify their existing system for non-destructive testing into one suitable for breast imaging, perform a physics evaluation and perform a small clinical pilot feasibility trial. The initiation of this project has been delayed by non-approval of the human use portion of the project. As of October, 2002, we have just received US Army Human Use approval for study of tissue samples. This has been resubmitted to the Georgetown IRB for approval of modifications requested by the US Army's reviewer. During this past year we provided technical advice to Imperium, but have not been able to conduct the detailed tests as planned. I am hopeful that the Georgetown IRB will agree to the changes requested by the US Army Human Subjects Reviewers so we can start.
During the wait for Human Use approval, we have been meeting with Imperium and they have improved the system that we will be testing. We will describe some of these improvements in this annual report.

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Table of Contents

High-Resolution Speckle-Free Ultrasound Imaging System--A potential solution for detecting missed beast cancer

Introduction

The Imperium Inc. transmission ultrasound system is a highly promising novel method for imaging the breast. In this pilot project, we are to work with Imperium to advise and help them modify their existing system for non-destructive testing into one suitable for breast imaging, perform a physics evaluation of the system and perform a small clinical pilot feasibility trial. The initiation of this project has been delayed by non-approval of the human use portion of the project. We modified the protocol as requested, obtained Georgetown IRB approval and resubmitted it to the Army. The Army reviewer then requested additional changes. Approval of these additional modifications was received for the initial portion of this study in October, 2002 from the US Army reviewer and the most recent modifications requested by the US Army reviewer are under review by the Georgetown IRB. During this past year we provided technical advice to Imperium, but have not been able to conduct the detailed tests as planned. I am hopeful that the Georgetown IRB will approve the latest version so that the project can start.

During this year, we have advised Imperium Inc., as they have worked to improve the system and broaden its applicability. Important modifications have been made in the design of the ultrasound source, lens design and improved dynamic range of the detector. The company has performed physics tests on the system as well.

Body

During the past year we have used only minimal funds because we did not have Army Human Subjects approval to begin the project. We have visited Imperium's R and D site and have worked with the system at Georgetown to learn how the controls operate and to suggest improvements that should be made prior to rigorous testing. The original system used a water bath. This has been supplemented by a dry system in which fluid filled stand-off pads are used to make contact with the artificial tissue under evaluation. We accompanied the company when they had an informal conference with the FDA. This was done to start their learning process of the requirements for eventual FDA approval. Safety information was extensively discussed and there appear to be no safety concerns.

Technical Report from the Company

c.3.1   Contrast Resolution

The ability of the camera to resolve separate tissue layers is a function of its sensitivity to small changes in amplitude. Imperium tested the camera's ability to resolve these small differences in detected signal level. The phantom used in this investigation was a custom-made Zerdine™-based phantom containing 3-mm and 5-mm spheres with small differences in attenuation from the surrounding background material. The phantom was manufactured by Computerized Imaging Reference Systems Inc. (CIRS, Norfolk, VA). The background material has an attenuation of 0.22 dB/cm/MHz that approximates the attenuation of fatty tissue [2, Table 4.6]. Two of the spheres were slightly less attenuating than the background and two of the spheres are slightly more attenuating than the background.

The ability to resolve amplitude differences is measured by calculating a Contrast to Noise Ratio (CNR), given by $CNR = (I_s - I_b) / \sqrt{(\sigma_s^2 + \sigma_b^2)/2}$, where the I_s and I_b are sphere and background mean intensities and σ_s and σ_b are the respective standard deviations. In these measurements, statistics for a block of image pixels inside and outside each sphere area were collected and analyzed. Transmission images were obtained with an Imperium I-100 camera, a two-

element aspheric 50 mm diameter F/1 (Imperium 915 series), and a 5.4-MHz center frequency, 1.5 in. diameter pulsed transducer. Figure 1 shows the images taken of this phantom.

| 3 mm | 3 mm | 5 mm | 5 mm |
| 0.06dB, 0.15dB | 0.5dB, 0.8dB | 0.06dB, 0.15dB | 0.5dB, 0.8dB |
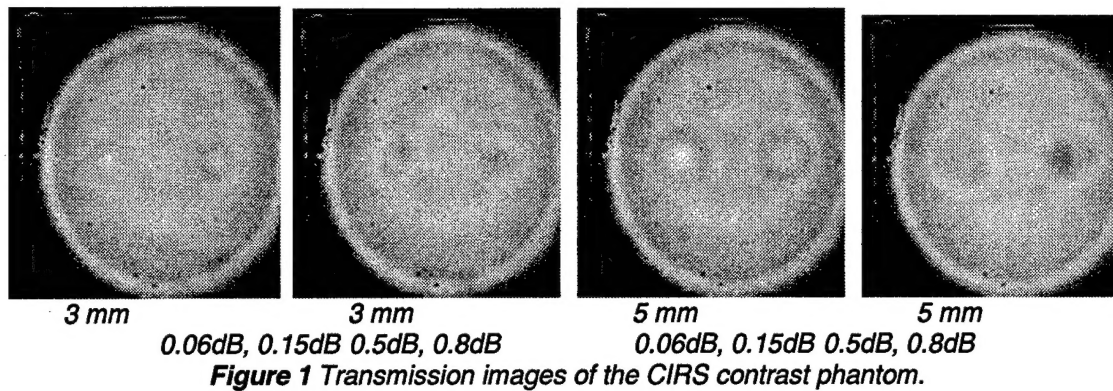
Figure 1 Transmission images of the CIRS contrast phantom.

The sphere diameters and their attenuations (dB/cm/MHz) are indicated in Figure 1. The overall circular field of view indicates the beam diameter. Note the edges around the spheres. The pronounced edges are caused by the refraction edge effect that tends to enhance object resolvability. This effect is known as phase contrast in gapped projection images [1].

The results of the CNR calculations are shown in Table 3. Note that there are 256 grayscale levels to represent pixel intensities. This phantom was designed to mimic the breast with embedded cysts and solid masses. The spheres with attenuation less than the background material mimic cysts in this phantom. The spheres with attenuation greater than the background material mimic solid masses.

Table 3
Contrast Resolution

| Sphere	Size (mm)	Differential Attenuation (dB)	Sphere Mean Intensity	Sphere Std. Dev.	Back-ground Mean Intensity	Back-ground Std. Dev.	Contrast	CNR
1	3	0.26	199	17	152	14	47	3.02
2	3	0.12	179	13	152	14	27	2.00
3	3	-0.45	117	11	154	16	-37	-2.69
4	3	-0.94	111	8	154	16	-43	-3.40
5	5	0.44	225	19	149	17	76	4.22
6	5	0.19	166	12	149	17	17	1.16
7	5	-0.75	138	12	157	17	-19	-1.29
8	5	-1.56	99	9	157	17	-58	-4.26

The contrast and CNR calculated in Table 3 must be viewed in the context of the amount of material contributed by the background and by the spheres. The attenuation of the background material is 0.22 dB/cm/MHz, the width of the phantom is 6 cm, and the center frequency of the transducer output is 5.4 MHz. The total attenuation through the phantom where there is no sphere is 7.13 dB. The differential attenuation column indicates the absolute difference between a phantom volume with no sphere and the phantom volume with spheres of different sizes and densities. The differential attenuation column in Table 3 is valid though the center of the sphere. Attenuation through off center sphere volumes will be closer to the background because there is less sphere material. It is notable that objects are resolvable with attenuation differences as small as 0.12 dB.
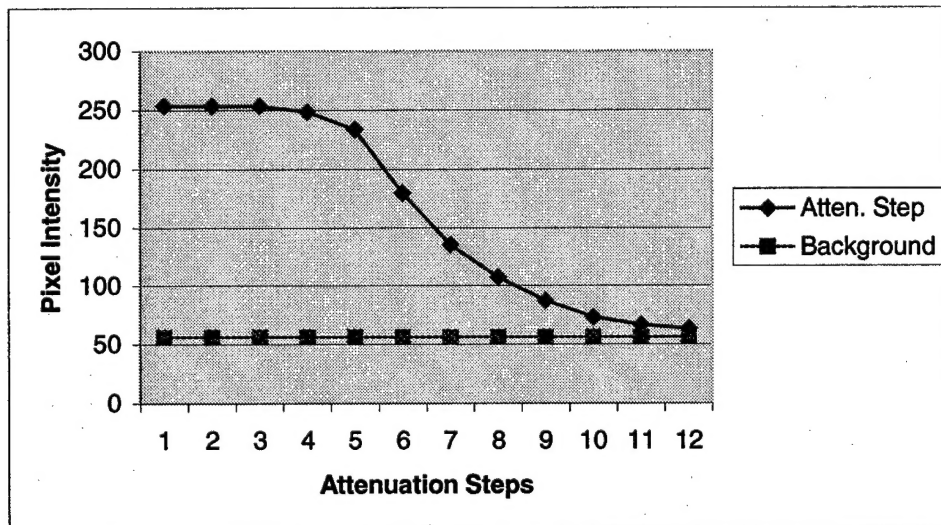
c.3.2 Dynamic Range

The dynamic range of the current system is set by the analog output of the camera and the 8-bit analog frame grabber used by the display system. The dynamic range of the next generation camera system is expected to be greater than 70 dB. The next generation camera will incorporate a 14-bit analog/digital converter (ADC) that will preserve the fidelity of the detector array in the accumulation of raw ultrasound data. We expect that the ultrasound data will be compressed to 8-10 bits for video display. Image compression techniques will be used to enhance the contrast resolution of the desired image area. With the use of a variable power output from the ultrasound transducer it is expected that the total dynamic range of the next generation camera will be well over 100 dB.

Twelve images were collected from a custom-fabricated dynamic range step phantom supplied by CIRS. These images are shown in Figure 2. A background pixel intensity of 57 was calculated by observing an area of the display in which there was a de-bonding of the piezo-electric material from the detector array. In this area there is no energy added to the pixel cells from ultrasound detection. Figure 3 shows a graph of pixel intensity versus the attenuation step. Each attenuation step is 2.7 dB.

The images were obtained with an Imperium I-100 camera, a two-element aspheric 50 mm diameter F/1 (Imperium 915 series), a 3.85 MHz center frequency, 1.5" diameter pulsed transducer. The peak sound pressure amplitude output from the transducer was 1.45 MPa.

| 2.7 dB | 5.4dB | 8.1dB | 10.8dB | 13.5dB | 16.2dB | 18.9dB | 21.6dB | 24.3dB | 27dB | 29.7dB | 32.4dB |
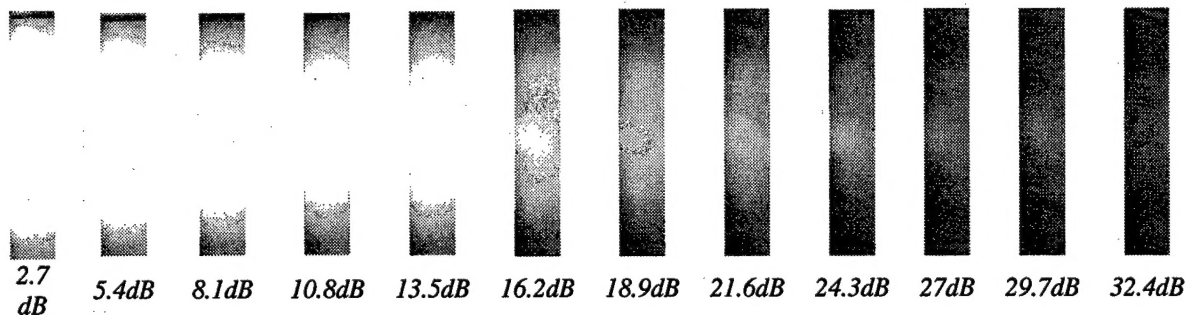
Figure 2. *Twelve steps of the dynamic range phantom with associated attenuation @ 3.85 MHz.*

Figure 3 *Dynamic Range of I100 Camera. Each attenuation step is 2.7 dB.*

As a comment on the dynamic range performance, the camera was able to penetrate 32.4 dB of phantom material. The attenuation of the material at 0.70 dB/cm/MHz approximates that of the average for soft tissue ([2], pg. 51). The phantom is 17.1 cm or 6.84 in. thick at the 32.4 dB step, the current Imperium ultrasound camera should then be capable of penetrating more than 6 in. of soft tissue in its current configuration. Greater sensitivity is expected in the next generation of camera. In mammography, the normal compressed breast thickness varies from 3 to 8 cm depending on breast size and breast density. Thus the dynamic range results support the feasibility of using the Imperium camera for breast imaging (17 cm penetrating ability vs. 8 cm for maximum usual breast thickness).

c.3.3 Spatial Resolution

The purpose of this task is to investigate the ability of the camera to resolve separate objects in a field of view, a function of its spatial resolution. The custom-fabricated Zerdine™-based CIRS phantom used in this investigation contains seven, 250 μm steel wires embedded in a fan shape. Transmission image data was obtained with an Imperium I-100 camera, a two-element aspheric 50 mm diameter F/1 (Imperium 915 series), and a 5.4-MHz center frequency, 1.5"-diameter pulsed transducer. Figure 4 shows an image taken of this phantom. Spatial resolution of the camera is determined by its ability to resolve the wires and the gaps between the wires.

The acoustic lenses designed by Imperium for its ultrasound cameras are diffraction limited. Eq. (1) describes the limit of resolution for the diffraction-limited lens used in this investigation.

$$D_L = 1.22\lambda F/D \qquad\qquad ...(1)$$

$\lambda = 277\,\mu m\ (5.4\ MHz)$
$D =$ diameter of the aperture $=$ diameter of the transducer $= 1.5\ in. = 3.75\ cm$
$F =$ Focal Length $= 50\ mm$
$D_L = 451\,\mu m$

The above computation indicates that the resolution of the system used for this investigation should be about 500 μm. Images shown in Figure 1 and results of work by Ishisaka et al [1] indicate that the phenomenon of phase contrast acts to enhance the edges of objects and may significantly improve the resolution achievable over the limit of Eq. 1.

Quantitative results of the first spatial resolution investigation are shown in Figure 5. The intensity of the steel wires is shown as the lower pixel values and the gaps between the wires are shown as the higher values. The center of the image in Figure 4 is 55 mm from the apex of the fan and the fan spreads at an angle of 4.77°. The distance between the outer two wires at the red line in Figure 4 is 9.17 mm. As can be seen, there is substantial blurring of the wires in the image. The aggregate width of seven, 250 μm wires is only 1.75 mm and so should account for only a small part of the width as seen in the image. The blurring is to be expected as the diameter of the wire is only half the spatial resolution predicted by Eq. 1. Observe that five of the six wire gaps are pronounced and one is obscured. This is due to an imperfection in the phantom. Two of the wires lay on top of each other.

The conclusion from this investigation is that we are limited by the operating frequency of the ultrasound camera. It is desirable that we should be able to resolve the 250 μm wires with no blurring. By doubling the frequency to 10 MHz it is predicted from Eq. 1 that we will be able to image the wires without blurring.

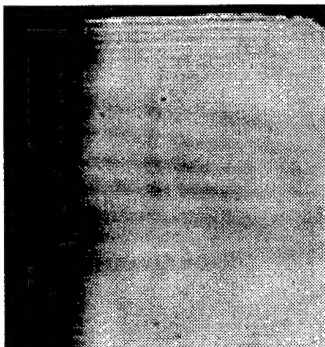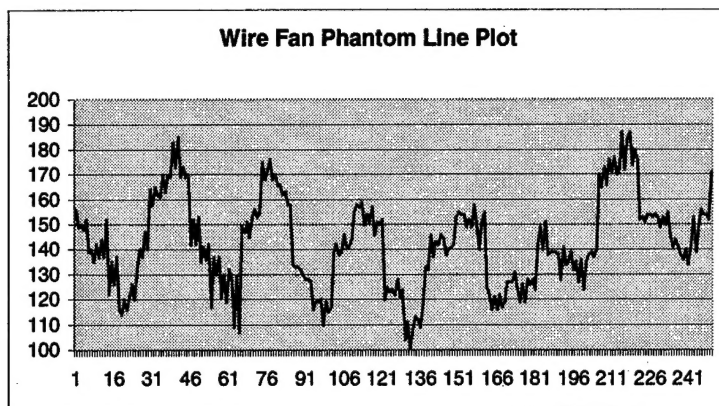**Figure 4** Wire Fan Phantom

Figure 5 *Fan Phantom Line Intensity Plot*

A second spatial resolution test was conducted with a CIRS microcalcification phantom. It consisted of Zerdine™ material with imbedded calcium carbonate inclusions with diameters 150-160, 250-280, 320-355, 425-450, and 710-850 μm. Camera images are shown in Figure 6.

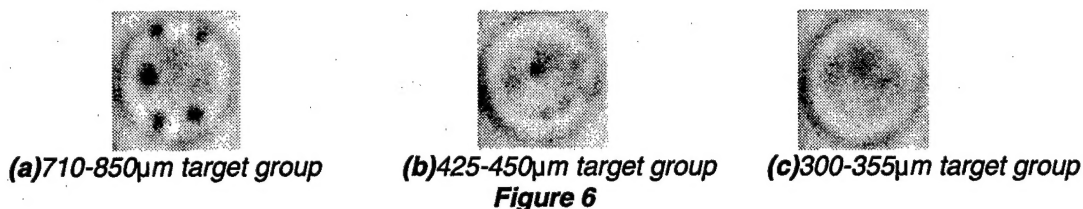*(a)710-850μm target group*   *(b)425-450μm target group*   *(c)300-355μm target group*

Figure 6

Figure 6a clearly shows 700 μm targets. 700 μm is greater than the calculated resolution and thus it is expected that the targets will be easily seen. Figure 6b shows the presence of 450 μm targets but the resolvability of the targets is strained. A single target is clearly seen and other targets are less clearly seen. Unfortunately, most of the targets in this phantom are placed on the lip of an Acrylic dish that holds the targets in place. This is unfortunate because there are refraction effects at the boundaries of this lip that make the targets hard to see. Figure 6c shows the presence of 300 μm targets. The targets in this phantom are blurred as would be expected when the targets are smaller than the resolution limit.

From Eq. 1 it can be seen that resolution can be improved by increasing the frequency, decreasing the focal length, or increasing the diameter of the lens. Decreasing the focal length of the system used in this investigation is impractical. With a lens diameter of 50 mm and a focal length of 50 mm, the current design utilizes a F1 lens. Implementing a smaller focal length would be difficult. Increasing the lens size is possible but there are mechanical limits due to the extended water path. Imperium is currently working on a 3-in. lens design and is investigating the feasibility of a 5 in. lens. One problem with increasing the lens diameter is that the focal length must necessarily increase.

The most practical way to improve resolution is to increase the ultrasound frequency. Eq. 1 is linear, so doubling the frequency to 10 MHz would result in a halving of the resolution to 244 μm. Imperium proposes that increasing the frequency to 13 MHz poses no significant technical problem. The issue in increasing the ultrasound frequency is the increase in attenuation. The tradeoff between increased attenuation and improved resolution will be evaluated in the context of imaging breast tissue. Most conventional B-scan ultrasound systems operate at 12-13 MHz for imaging the human breast so the use of frequencies higher than 10 MHz is likely for the proposed system.

c.3.4 Zoom Lens Results

The ultrasound imaging system was set up and focused in a manner typically used for imaging with Imperium's ultrasound camera. The transducer was fixed in a position approximately 18 in. from the camera. The two lens elements are Imperium's two-element aspheric 2.75 in. diameter F/1 (Imperium 915 series) lens. Lens elements were

moved relative to one another to achieve zoom. The change in image size and the lens positions were recorded. Image size was measured using the AcoustoVision Measurement™ tool (Imperium, Inc.).

Figure 7 shows the relationship of lens movement to image size. Note the monotonic change in image size versus lens change. This relationship is necessary to realize a practical zoom lens design
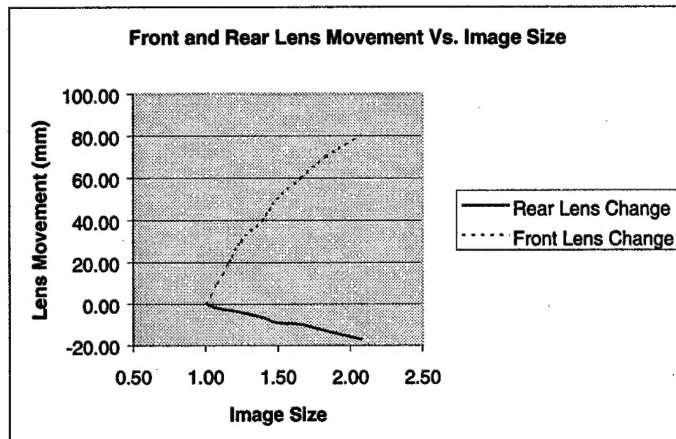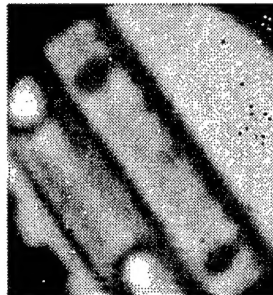

Figure 7 Lens Movement vs. Image Size

A 2:1 zoom was accomplished using a standard lens system by increasing the on-axis distance between the lenses. The front lens moved a distance of 80 mm and the rear lens moved 17 mm from the starting position. The images in Figure 8 show the reference image at the start and end points of the lens positions. Note the enlargement of the 1-in. marks on the ruler in Figure 8b.
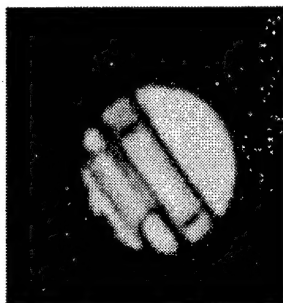
Figure 8a Image With no Magnification   **Figure 8b** Magnified Image

c.3.5   Large (3") Field Of View

Two large area-imaging lenses were designed using the Zemax Optical Design Program (Focus Software Inc, Tucson, AZ). Both lens systems are composed of a large diameter objective lens and two smaller focusing elements. The lenses were designed to be diffraction-limited across the surface of the lens. Based on the design in Figure 9, the blur spot size at any given point in the image plane should be no greater than 375 μm for a lens with a three inch diameter, F/1 speed, and an ultrasound frequency of 5.0 MHz. Spot size estimates were performed for several points across the lens surface with the largest spot size occurring at the point farthest from the paraxial axis. The size of the plane wave to be focused and the size of the sensor array determine the magnification of the lens design. In this case, the lens focused a 76.2 mm diameter wave front onto a 10.8 mm square sensor array yielding a magnification of 0.14.

$$m = h'/h = 10.8 \text{ mm} /76.2 \text{ mm} = 0.14. \qquad \qquad \dots (2)$$

m = magnification
h' = image height
h = object height

The first design consisted of two elements from the Imperium 915 lens with the addition of a third larger diameter objective lens. The working F-number of this design is 1.69 with an estimated off axis blur size of 375 μm. The Zemax Optical design program generated the ray tracing and spot size diagrams shown in Figure 9.
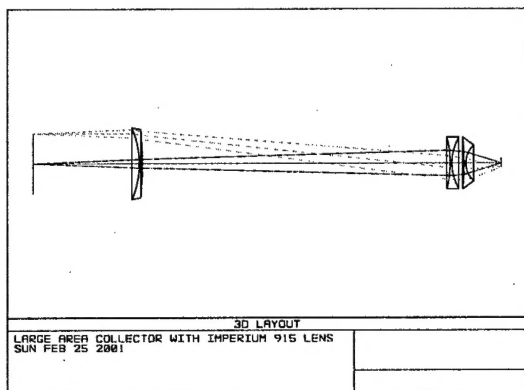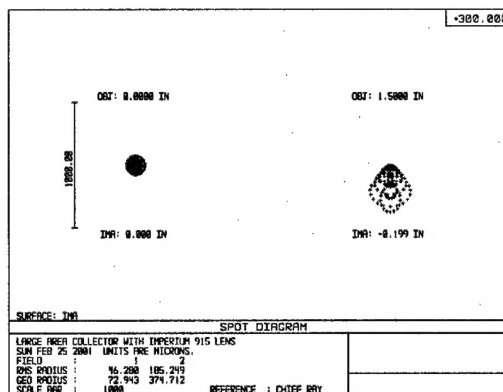

Figure 9a *3-in. Lens, Ray Tracing*

Figure 9b *3-in. Lens with 375 micron spot size*

A second, improved design is similar but consists of three newly designed lens elements. The working F-number of this design is 1.68 with an estimated off axis blur size of 150 μm. Ray tracing and spot size diagrams of the second design are shown in Figure 10.
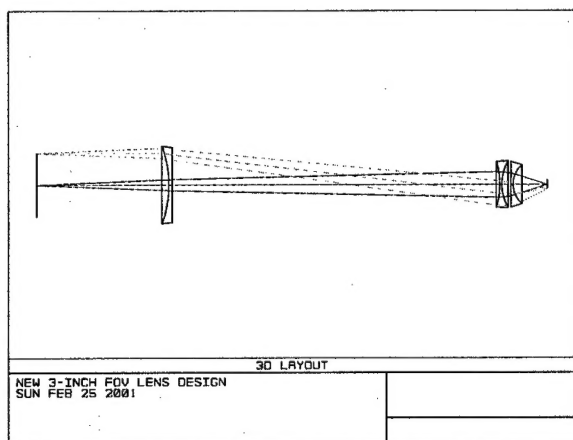
Figure 10a *3-in. Lens, Ray Tracing*
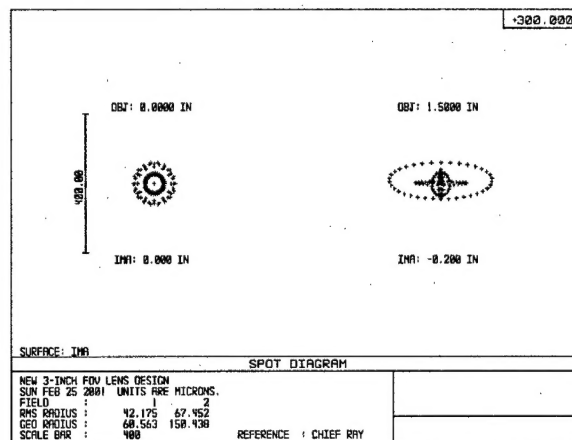
Figure 10b *3-in. Lens with 150 micron spot size*

c.4 Dry System Implementation

A dry system (no water tank) is required as a practical approach to implementation of a through transmission ultrasound system for medical applications. Imperium has therefore designed and constructed a proof of concept C-arm system in which the ultrasound camera and source transducer are placed on opposing ends of a C-arm mount. The patient is placed between the camera and source for imaging. As discussed in section c.1, this proof of concept design will serve as a foundation for the fabrication of a clinical breast imaging system to be developed in Phase II of this effort. A picture of the prototype dry system is shown in Figure 11.

The C-arm system is designed to provide a means of dry-coupling a patient to an Imperium ultrasound camera in the through-transmission configuration. The system has several degrees of freedom to allow it to move into a convenient position for patient coupling. There are flexible acoustic coupling pads on the transducer and camera sides of the device to provide a comfortable, conformable interface with a variety of irregularly shaped objects. The entire C-arm is mounted to a wheeled cart for added mobility. User interface is accomplished with a standard monitor, keyboard and mouse, along with typical pulser controls.
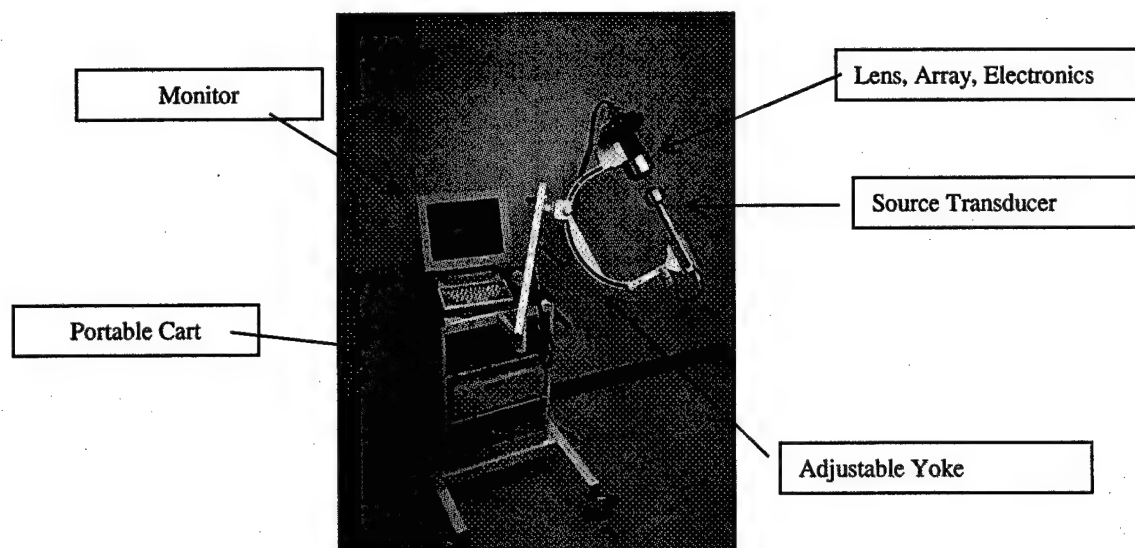
Figure 11 Proof of Concept C-arm System

c.5. Improvements in Source Pulsers and Transducers

In order to meet our unique requirements for high-amplitude, wide-area ultrasonic fields, we have designed and built our own small, low-cost, high-voltage pulsers. The pulser design generates a 100 ns pulse with an amplitude variable from 0v to 1 Kv. We will increase the voltage amplitude to 2 Kv. Because of the low impedance of the required high-frequency, large-area source transducers, driving the transducers is difficult with a single pulser driver circuit. We are investigating the use of arrays of multiple smaller transducers each driven by a separate pulser circuit.

An interesting finding is that broadband composite transducers may be detrimental to this application. The lower attenuation at lower frequencies results in loss of spatial resolution. Narrowband ceramic transducers appear to produce a sharper picture. Figures 12a and 12b show the frequency responses of a ceramic and composite transducers respectively. The peaks in Figure 12A are at 4.48 MHz and 5.78 MHz with attenuated low frequency response. The edges of the passband in Figure 12b are at 3.83 MHz and 6.96 MHz.
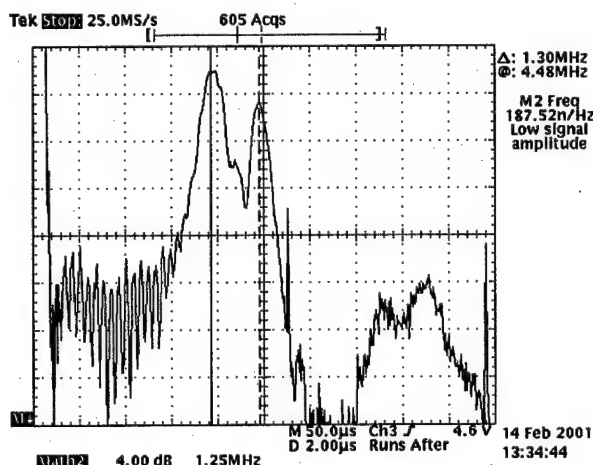

Figure 12a Narrowband Ceramic Transducer
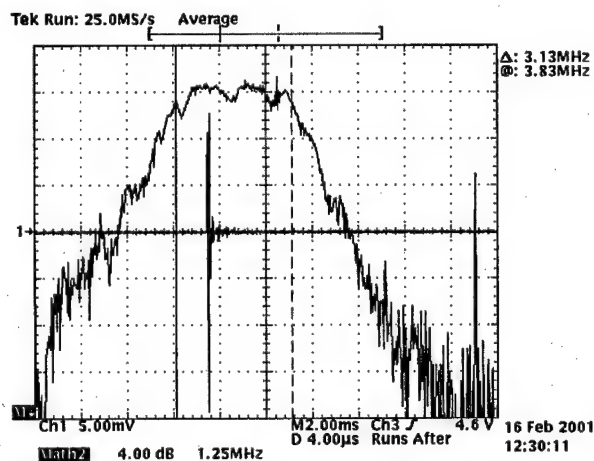
Figure 12b Broadband Composite Transducer

c.5 Tissue Imaging

c.5.1 Mouse Imaging

A recently sacrificed C3H/HeJ male mouse weighing 17 gm was positioned for transmission imaging as shown below in Figure 14a and then immersed in a water tank. Transmission images were obtained with an Imperium I100 camera, a two-element aspheric 50 mm diameter F/1 and a 5.4-MHz center frequency, 1.5 in. diameter pulsed transducer. Figure 13b shows the thorax.

Spinal Column   Ribs   Lungs
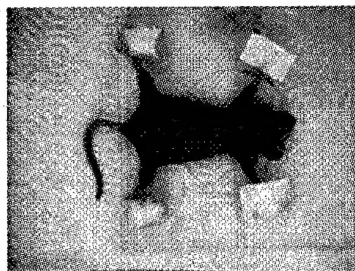
Figure 14a *Mouse pictured just prior to Imaging.*

Figure 13b *Mouse thorax imaged by the I-100 Camera.*

It is expected that the resolution of the proposed device for applications in breast imaging as well as in small animal imaging would be markedly improved with the use of higher-frequency ultrasound. This is being proposed for Phase II.

c.5.2 Simulated Breast Biopsy

To prove the feasibility of using the proposed device in image guided needle biopsy we have performed imaging with a breast phantom. The images in Figures 14a and 14b were taken by Dr. Christopher Merritt of Thomas Jefferson University. The images are of a 1 cm fatty mass with needle embedded in a gelatin phantom. In Figure 14a notice the surface reflection at the bottom of the image, the reverberations from the needle, and the presence of speckle. These are common artifacts of pulse echo ultrasound. Figure 14b which was taken with the through transmission camera from Imperium clearly shows the needle and mass.


Figure 14a *Pulse Echo Ultrasound Image Needle in gelatin phantom*
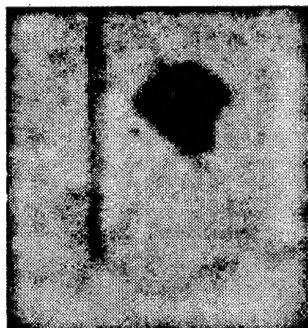
Figure 14b *Transmission Ultrasound Image Needle in phantom next to 1cm mass.*

A second set of images was taken with a CIRS phantom at the Georgetown University Medical Center. Figure 15 shows the sequence of needle biopsy images. The images were sampled from a sequence of 150 ultrasound images taken from 30 frames per second for five seconds. The Imperium ultrasound camera was focused on two small simulated masses and a biopsy needle about 4 cm below the surface. The needle first punctured the target (a) and (b), then left (c), and punctured the target again (d) and (e). The needle was rotated clockwise from (e) to (f). This operation pushed the mass on the right upper corner out of the focal plane.

(a)   (b)   (c)   (d)   (e)   (f)
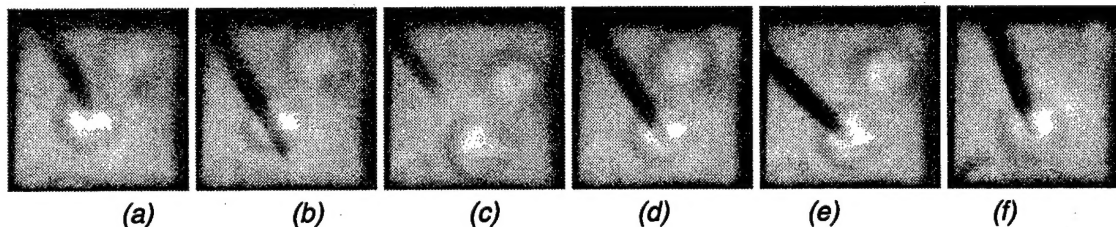
Figure 15 *Needle Biopsy Sequence*

End of Section on Company's feasibility testing.

Key Research Accomplishments

Because we did not have Human Subjects approval to proceed, we were unable to start the project. Based on our advise the company is making improvements in the user interface and the mechanical functioning of the C-arm that supports the device when it is in use. The sections from the company's technical report provide additional information that the system is improving and that the proposed clinical tests in tissues samples should proceed. We now have US Army approval to proceed, but because the protocol was modified during the Army review, the Georgetown IRB must re-approve it.

Reportable Outcomes

None to date

Other

One of our graduate students, Chu-Chuan Liu received a Pre-Doctoral Fellowship Award (# DAMD17-01-0197) from the US Army Breast Cancer Program to perform his research on the technical aspects of the Imperium Transmission Ultrasound System. He presented a poster on this at the US Army Breast Cancer Era of Hope Conference in Orlando, FL, Sept 25-28, 2002. A copy of the poster is attached.

Conclusions

During the delay in initiation of this project, we have seen significant improvement in the design and operating characteristics of the Imperium C-Scan Transmission Ultrasound system. I am hopeful that the Human Subjects protocol changes requested by the US Army Reviewer will receive approval from Georgetown's IRB within the next 2 months. I would very much like to officially start this most important project. Due to the delays, I have previously requested a no-cost time extension of this project.

References:

[1]   *Ishisaka A, Ohara H, and Honda C, " A New Method of Analysis Edge Effect in Phase Contrast imaging with Incoherent X-rays," Optical Review, Vol. 7, No. 6, pp.566-572, 2000.*

[2]   *McDicken WN, "Diagnostic Ultrasonics" Third Edition, Churchhill Livingstone, 1991.*

Appendices: Copy of poster from Department of Defense Era of Hope Meeting, Orlando, FL September 25-28, 2002.

AN ATTENUATION-BASED ULTRASOUND SYSTEM USING A PIEZOELECTRIC SENSING MICROARRAY AND ITS POTENTIAL FOR IMAGING THE BREAST

Chu-Chuin Liu, Ph.D.
Shih-Chung B. Lo, Ph.D.
Marvin E. Lasser, Ph.D.
Matthew T. Freedman, M.D.
Yue Wang, Ph.D.

Department of Electrical Engineering and Computer Science,
The Catholic University of America, Washington, D.C. 20064

ISIS Center, Department of Radiology, Georgetown University,
Research Center, Washington D.C. 20007

Imprinted on: Silver Spring, Maryland 20903

Abstract

Introduction

Material and Methods

Detectability of Masses

Figure 5. The C-Scan images of four 3-mm spheres using Zerdine™ background at 0.22 dB/cm² MHz. (A) Cysts mimicking spheres with 0.06 dB/cm²MHz at the left and 0.15 dB/cm²MHz at the right. (B) Tumor mimicking spheres with 0.5 dB/cm²MHz at the left and 0.8 dB/cm²MHz at the right.

Figure 6. The C-Scan images of four 3-mm spheres using Zerdine™ background at 0.22 dB/cm² MHz. (A) Cysts mimicking spheres with 0.06 dB/cm²MHz at the left and 0.15 dB/cm²MHz at the right. (B) Tumor mimicking spheres with 0.5 dB/cm²MHz at the left and 0.8 dB/cm²MHz at the right.

Detectability of Microcalcifications

Figure 7. Images of the C-scan system for the three sets of diamond calcifications setting in breast tissue-mimicking Zerdine™. (A) 0.7-0.85 mm clustered calcifications. (B) 0.4-0.6 mm clustered calcifications. (C) 0.3-0.35 mm clustered calcifications.

Figure 8. ROIs and their intensity and CNR measures for the smaller clustered calcifications. (A)Four intensity measures for the calcifications upper-right corners and the intensity (noise level) measures of selected background areas.(B) Estimated CNR values of the four calcifications.

Fan Lines as a Test Target

(A) A fan pattern is constructed by 7 stainless steel wires. Each wire is 250 micron thickness.

Figure 9. A fan-lines phantom is shown in (A). Image of the fan-lines is (B), the inverted intensity profile in (C) at 0.26 mm spacing at the level indicated by the yellow line in (B).

Figure 10.(A) Image of the fan-lines in Figure 11(A), the inverted intensity profile in (C) at 0.26 mm spacing at the level indicated by the yellow line in (A).

Figure 11.(A) Image of the fan-lines in Figure 9(A), the inverted intensity profile in (C) at 0.50 mm spacing at the level indicated by the yellow line in (A).

A C-Scan Image Sequence

Figure 12.A C-scan image sequence of human finger.

Compensation for Inactive Pixels

Figure 13. A point detector was used to automatically detect inactive pixels followed by a compensation processing. (A)Background image without phase. (B) Phased background image. (C)FIXED Original test images. (D)FIXED Final images.
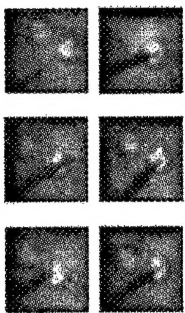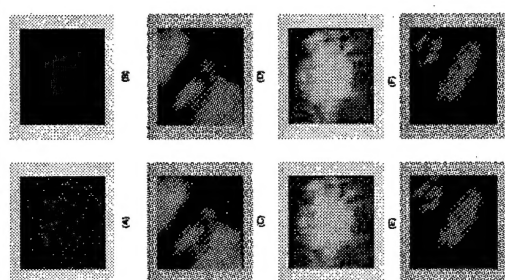
Breast Biopsy Simulation

Figure 14. The above images were sampled from a sequence of 150 ultrasound images taken from 30 frames per second for two seconds of a CHS breast phantom. The C-scan ultrasound shows the biopsy needle about 4 cm below the surface.

Figure 15. These images are of a specific detail in the Computational Image Reference System (CIRS) breast ultrasound phantom Model 551 designed for demonstrating the resolution and artifact speckle artifacts.

Conclusion And Discussion

Acknowledgments

Figure 1. Schematic of array annealed array

Figure 2. 128 x 128 annealed array

Figure 3. The prototype system configuration

Figure 4. Laboratory setting in a water tank